

AMENDED IN SENATE JUNE 30, 2009

AMENDED IN ASSEMBLY MAY 11, 2009

AMENDED IN ASSEMBLY MAY 5, 2009

AMENDED IN ASSEMBLY APRIL 13, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 995

Introduced by Assembly Member Block

February 27, 2009

An act to amend Section ~~1639.01~~ of, and to add Section ~~1643.3~~ to, ~~1635.1~~ of the Health and Safety Code, relating to tissue banks.

LEGISLATIVE COUNSEL'S DIGEST

AB 995, as amended, Block. Tissue bank licensing.

Existing law requires all tissue banks, with certain specified exceptions, to be licensed by the State Department of Public Health.

This bill would add to the list of licensure exceptions the storage of federal Food and Drug Administration (FDA)-regulated tissue-engineered products by a person licensed to provide health care services, acting within the scope of their license and practicing in a lawful practice setting, provided that the federal FDA-regulated tissue-engineered product has been obtained from a licensed tissue bank and is stored in strict accordance with federal FDA regulations and guidelines and is used for the express purpose of implantation into or application on a patient and is not intended for further distribution.

~~Existing law requires the State Department of Public Health to establish regulations, as specified, governing the operation and maintenance of tissue banks licensed in California. Existing law allows~~

for the revocation or suspension of a tissue bank's license for specified reasons. Violation of these provisions is a misdemeanor.

~~This bill would require the collection, processing, storage, or distribution of human tissue by licensed tissue banks and tissue for use in California to comply with the 12th edition of Standards for Tissue Banking as published by the American Association of Tissue Banks, and would require future amendments of these standards to be evaluated and considered for adoption by the department pursuant to a specified process. This bill would also allow the department to impose on licensed tissue banks, as an alternative to suspension or revocation of a tissue bank's license, a civil administrative penalty of \$100 per day of noncompliance per violation not to exceed an aggregate of \$3,000 per day.~~

~~Because the bill would make changes to the definition of a crime, it constitutes a state-mandated local program.~~

~~The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.~~

~~This bill would provide that no reimbursement is required by this act for a specified reason.~~

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: ~~yes~~no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1635.1 of the Health and Safety Code is
2 amended to read:

3 1635.1. (a) Except as provided in subdivision (b), every tissue
4 bank operating in California on or after July 1, 1992, shall have a
5 current and valid tissue bank license issued or renewed by the
6 department pursuant to Section 1639.2 or 1639.3.

7 (b) This chapter shall not apply to any of the following:

8 (1) The collection, processing, storage, or distribution of human
9 whole blood or its derivatives by blood banks licensed pursuant
10 to Chapter 4 (commencing with Section 1600) or ~~any~~ a person
11 exempt from licensure under that chapter.

12 (2) The collection, processing, storage, or distribution of tissue
13 for autopsy, biopsy, training, education, or for other medical or
14 scientific research or investigation, where transplantation of the
15 tissue is not intended or reasonably foreseeable.

(3) The collection of tissue by an individual physician and surgeon from his or her patient or the implantation of tissue by an individual physician and surgeon into his or her patient. This exemption shall not be interpreted to apply to any processing or storage of the tissue, except for the processing and storage of semen by an individual physician and surgeon when the semen was collected by that physician and surgeon from a semen donor or obtained by that physician and surgeon from a tissue bank licensed under this chapter.

(4) The collection, processing, storage, or distribution of fetal tissue or tissue derived from a human embryo or fetus.

(5) The collection, processing, storage, or distribution by an organ procurement organization (OPO), as defined in Section 485.302 of Title 42 of the Code of Federal Regulations, if the OPO, at the time of collection, processing, storage, and distribution of the organ, has been designated by the Secretary of Health and Human Services as an OPO, pursuant to Section 485.305 of Title 42 of the Code of Federal Regulations, and meets the requirements of Sections 485.304 and 485.306 of Title 42 of the Code of Federal Regulations, as applicable.

(6) The storage of prepackaged, freeze-dried bone by a general acute care hospital.

(7) The storage of freeze-dried bone and dermis by ~~any~~ a licensed dentist practicing in a lawful practice setting, providing that the freeze-dried bone and dermis has been obtained from a licensed tissue bank and is stored in strict accordance with a kit's package insert and any other manufacturer instructions and guidelines and is used for the express purpose of implantation into a patient.

(8) The storage of federal Food and Drug Administration (FDA)-regulated tissue-engineered products by a person licensed to provide health care services, acting within the scope of their license and practicing in a lawful practice setting, provided that the federal FDA-regulated tissue-engineered product has been obtained from a licensed tissue bank and is stored in strict accordance with federal FDA regulations and guidelines and is used for the express purpose of implantation into or application on a patient and is not intended for further distribution.

~~SECTION 1. Section 1639.01 of the Health and Safety Code is amended to read:~~

1 ~~1639.01.— (a) Notwithstanding Section 1639, no person shall~~
2 ~~engage in the collection, processing, storage, or distribution of~~
3 ~~human tissue unless the tissue is collected, prepared, labeled,~~
4 ~~stored, and distributed in accordance with the standards set forth~~
5 ~~in the 12th edition of Standards for Tissue Banking as published~~
6 ~~by the American Association of Tissue Banks and in effect on May~~
7 ~~1, 2008. These shall be the standards for all licensed tissue banks~~
8 ~~operating in California or providing tissue to be used in California.~~

9 ~~(b) Consistent with the purposes of this chapter, the department~~
10 ~~shall evaluate updates to the standards made by the American~~
11 ~~Association of Tissue Banks, including later editions. Proposed~~
12 ~~changes to the standards shall be posted on the department's~~
13 ~~Internet Web site at least 45 days prior to their adoption. Public~~
14 ~~comment shall be accepted by the department for at least 30 days~~
15 ~~after posting. If a member of the public requests a public hearing~~
16 ~~during the 30-day posting period, the hearing shall be held prior~~
17 ~~to the adoption of the proposed changes. Comments received shall~~
18 ~~be considered prior to the posting of final changes. Adoption of~~
19 ~~changes by the department pursuant to this subdivision shall not~~
20 ~~be subject to the rulemaking requirements of Chapter 3.5~~
21 ~~(commencing with Section 11340) of Part 1 of Division 3 of Title~~
22 ~~2 of the Government Code and written responses to public~~
23 ~~comments shall not be required.~~

24 ~~SEC. 2.— Section 1643.3 is added to the Health and Safety Code,~~
25 ~~to read:~~

26 ~~1643.3.— As an alternative to revocation or suspension of a~~
27 ~~license issued under this chapter, the department may impose an~~
28 ~~alternative civil administrative penalty of one hundred dollars~~
29 ~~(\$100) per day of noncompliance per violation, including an~~
30 ~~immediate jeopardy, violation except that the aggregate penalty~~
31 ~~per day shall not exceed three thousand dollars (\$3,000). This~~
32 ~~penalty may be imposed only after notice and an opportunity to~~
33 ~~respond in accordance with Section 100171.~~

34 ~~SEC. 3.— No reimbursement is required by this act pursuant to~~
35 ~~Section 6 of Article XIII B of the California Constitution because~~
36 ~~the only costs that may be incurred by a local agency or school~~
37 ~~district will be incurred because this act creates a new crime or~~
38 ~~infraction, eliminates a crime or infraction, or changes the penalty~~
39 ~~for a crime or infraction, within the meaning of Section 17556 of~~
40 ~~the Government Code, or changes the definition of a crime within~~

1 ~~the meaning of Section 6 of Article XIII B of the California~~
2 ~~Constitution.~~

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